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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,502	02/12/2007	Anita Mehta	RLL-290US	2259

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EXAMINER	
NOLAN, JASON MICHAEL	

ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,502	MEHTA ET AL.	
	Examiner	Art Unit	
	JASON M. NOLAN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15-17 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15-17 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicants Amendment – After Non-Final Rejection, filed **12/05/2007**. **Claims 1-10, 15-17, & 27** are pending in the instant application; of which, **Claims 1-10, 15, 17, & 27** are currently amended. **Claims 11-14, 18-26, & 28-36** are canceled.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Response to Amendment

Applicant's amendments, with respect to **Claims 1-10, 15, 17, & 27** have been fully considered and are entered. The 112-enablement rejection of **Claims 1-4, 7-10, 17, & 27**; the 112-enablement rejection of **Claims 7-10, & 15**; and the objection to **Claim 5** are withdrawn per amendment. The ODP rejection over US Patent No. **7,232,835** is withdrawn per TD; however, the provisional ODP rejections over US Serial Nos. **10/543,585**; **10/552,456**; **10/544,520**; and **10/502,573** are maintained herein.

Terminal Disclaimer

The terminal disclaimer filed on **12/05/2007** disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of US Patent No. **7,232,835** has been reviewed and is accepted. The terminal disclaimer

has been recorded. The obviousness-type double patenting rejection of **Claims 1-10, 15-17, & 27** over the '**835** Patent is withdrawn per TD.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 15-17, & 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **Claims 1-14, 21, & 23-32** of US Serial No. **10/543,585**. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter. The compounds of the current application are not patentably distinct from those of the **'585** application because of the significant overlap within formula I of each case. Therefore, potential infringements upon the instant application would also be infringements upon the **'585** application.

Claims 1-10, 15-17, & 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **Claims 1-4, 6, & 8-14** of US Serial No. **10/552,456**. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter. The compounds of the current application are not patentably distinct from those of the **'456** application because of the significant overlap within formula I of each case. Therefore, potential infringements upon the instant application would also be infringements upon the **'456** application.

Claims 1-10, 15-17, & 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **Claims 1-17** of US Serial No. **10/544,520**. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter. The compounds of the current application are not patentably distinct from those of the **'520** application because of the significant overlap within formula I of each case, (specifically, when **Q** = bond). Therefore, potential infringements upon the instant application would also be infringements upon the **'520** application. *Note*: the structure of Formula I in the **'520** application appears to be incorrect, (it is missing a bond, making it monocyclic). However, it appears to Examiner that the bond should be there because the synthetic precursor to Formula **I** is Formula V, which contains the bond. Further, the species in Claim 2 are bicyclic: 3-azabicyclo[3.1.0]-hexyl derivatives and appear on the search report as bicyclic compounds.

Claims 1-10, 15-17, & 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **Claims 1-12, 18, & 20-29** of US Serial No. **10/502,573**. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter, (specifically when **Q** = $(CH_2)_n$, **n** = 0, and **Z** = NR_{10}). The compounds of the current application are not patentably distinct from those of the **'573** application because of the significant overlap within formula I of each case. Therefore, potential infringements upon the instant application would also be infringements upon the **'573** application.

Claim Rejections - 35 USC § 112

Claim 15 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for compositions and a method of *treatment* for some diseases or disorders of the respiratory, urinary and gastrointestinal systems, (such as those listed in **Claim 16**: urinary incontinence, lower urinary tract symptoms (LUTS), bronchial asthma, chronic obstructive pulmonary disorders (COPD), pulmonary fibrosis, irritable bowel syndrome, obesity, diabetes and gastrointestinal hyperkinesis), it does not reasonably provide enablement *for the treatment* for any diseases or disorders of the respiratory, urinary and gastrointestinal systems. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The nature of the invention

The nature of the invention is compounds and compositions of formulae I-IV, the process for preparing these compounds, and methods of using these compounds.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art, namely pharmacological art, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent

one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. *In the instant case*, the claimed invention is highly unpredictable since one skilled in the art would recognize that a group of compounds and compositions may provide a treatment for conditions such as urinary incontinence, lower urinary tract symptoms (LUTS), bronchial asthma, chronic obstructive pulmonary disorders (COPD), pulmonary fibrosis, irritable bowel syndrome, obesity, diabetes and gastrointestinal hyperkinesis, but it does not mean that the same group of compounds and compositions may prevent said conditions.

The amount of direction or guidance present and the presence or absence of working examples

The direction or guidance present in Applicants' Specification for a method of using the compounds and compositions of formulae I-IV to *treat* clinical conditions such as urinary incontinence, lower urinary tract symptoms (LUTS), bronchial asthma, chronic obstructive pulmonary disorders (COPD), pulmonary fibrosis, irritable bowel syndrome, obesity, diabetes and gastrointestinal hyperkinesis is found on pages 14-16.

The breadth of the claims, quantity of experimentation, and level of skill in the art

Claim 15 is drawn to the treatment of an animal suffering from any and/or all diseases or disorders of the respiratory, urinary and gastrointestinal systems. The breadth of said claim would require undue experimentation to determine the multiple patient populations, determination of which of a plethora of potential compounds (formulae I, II, III, or IV) to administrate, and which of the plethora of diseases/disorders pertaining to the generic respiratory, urinary and gastrointestinal systems are responsive to said administration.

Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success. Examiner suggests incorporating the limitations of **Claim 16** into **Claim 15** to overcome this rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^{c}Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626

/Jason M. Nolan, Ph.D./
Examiner, Art Unit 1626